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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,103	06/18/1999	KAREN M. DOWNS	960296.95912	7263
26710	7590	12/09/2003	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497			WILSON, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/336,103

Applicant(s)

DOWNS, KAREN M.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 16, 18 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 15, 16, 18 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-16-03 has been entered. Applicant's arguments therein have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restriction***

This application contains claims 1-13, 15, 16, 18 and 29 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 27 and 28 are under consideration.

### ***Claim Rejections - 35 USC § 102***

I. Claims 27 and 28 remain rejected under 35 U.S.C. 102(b) as being anticipated by Downs (Feb. 1995, Development, Vol. 121, pages 407-416) for reasons of record.

Downs taught isolating allantoic tissue, culturing the tissue *in vitro*, transplanting the allantoic tissue to an embryo and observing the allantois, specifically observing the vasculogenesis of the allantoic stump (pg 408, col. 2; pg 409, col. 1, para. 1; pg 411,

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para. bridging col. 1 and 2, and Fig. 4B, see caption, line 13, "(B) 6  $\mu$ m histological section of the allantoic stump in the operated conceptus of A showing early vasculogenesis within the stump (arrowhead)"). Treating allantoic tissue with a compound as claimed is equivalent to contacting the allantoic tissue with an embryo as taught by Downs. In addition, Downs treated the allantoises with [ $^3$ H]methyl thymidine (page 408, col. 2, para. 3) and observed the effect of [ $^3$ H]methyl thymidine on growth and development (page 409, col. 1, line 14). Claim 27 is included because the embryo inherently has proteins.

Applicants argue Downs did not teach observing vasculogenesis originating in the allantois as opposed to vasculogenesis, which may originate elsewhere. Applicants' argument is not persuasive because Fig. 4B shows Downs observed "early vasculogenesis within the stump". The vasculogenesis is "originating in the allantois" as claimed because it occurs in the allantoic stump which is part of the allantois.

Applicants argue the reference does not demonstrate that allantoic mesoderm forms blood vessel *de novo* as would be required to demonstrate "vasculogenesis" as opposed to "vascularization." Applicants' argument is not persuasive. The claim does not require the allantoic mesoderm forms blood vessels *de novo*. Nor is it readily apparent that *de novo* blood vessel formation from the allantoic mesoderm is required to establish "vasculogenesis" has occurred because Downs specifically states "vasculogenesis within the stump" of the allantois occurs.

Applicants argue the present invention is based on the discovery described in Downs (2001) that "the murine allantois vascularizes initially by vasculogenesis rather

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than by invasion from the vitelline or fetal vasculatures.” Applicants’ argument is not persuasive because the claim only requires vasculogenesis originating the allantois; how vasculogenesis occurred (i.e. the mechanism of action) is not required in the claim. If this discovery is the basis of the application, then the observation of vasculogenesis in Downs must inherently be “vasculogenesis” and not “invasion from the vitelline or fetal vasculatures” whether or not it was known at the time of Downs in 1995.

Applicants argue the term "vasculogenesis" in Downs (1995) was in error as stated in the declaration by Downs filed 5-14-03. Applicants' argument is not persuasive. One of ordinary skill in the art at the time Downs (1995) was available would have recognized that "vasculogenesis" described by Downs (1995) was the genesis of blood vessels and not the regeneration of blood vessels because "vasculogenesis" means an event that is the beginning of blood vessel formation. Applicants argue the term “vasculogenesis” in Downs meant “vascularization” and not “allantoic mesoderm forms blood vessels ‘de novo’.” Applicants’ argument is not persuasive. The claims do not require formation of blood vessels from the allantoic mesoderm *de novo*. In addition, it is not readily apparent that the use of "vasculogenesis" was in error in Downs (1995) or that "vasculogenesis" should have been limited to --regeneration of blood vessels—or to *de novo* formation of blood vessels from the allantoic mesoderm.

### ***Conclusion***

This is an RCE of applicant's earlier Application No. 09/336103. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had

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been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL WILSON**  
**PRIMARY EXAMINER**